4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Change of Sponsor; Estradiol; Estradiol Benzoate and Testosterone Propionate; Progesterone and Estradiol Benzoate; Trenbolone Acetate; Trenbolone Acetate and Estradiol; Melengestrol; Ractopamine; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 17 new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) for various steroid ear implants for cattle and for melengestrol acetate liquid Type A medicated article and use in combination medicated feeds for heifers fed in confinement for slaughter from Ivy Laboratories, Division of Ivy Animal Health, Inc., to Elanco Animal Health, Division of Eli Lilly & Co.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, has informed FDA that it has transferred ownership of, and all rights and interest in, the NADAs and ANADAs in this table to Elanco Animal Health, Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.

NADA/ ANADA	Proprietary Name (established name)	21 CFR Section
110-315	COMPONENT E-C (progesterone and estradiol benzoate) with TYLAN (tylosin tartrate) COMPONENT E-S (progesterone and estradiol benzoate) with TYLAN (tylosin tartrate)	522.1940
118-123	COMPONENT 200 (estradiol benzoate) ENCORE (COMPUDOSE 400) (estradiol benzoate)	522.840
135-906	COMPONENT E-H (estradiol benzoate and testosterone propionate) with TYLAN (tylosin tartrate)	522.842
200-221	COMPONENT TE-IS (trenbolone acetate and estradiol) COMPONENT TE-S (trenbolone acetate and estradiol) COMPONENT TE-G (trenbolone acetate and estradiol) COMPONENT TE-IS (trenbolone acetate and estradiol) with TYLAN (tylosin tartrate) COMPONENT TE-S (trenbolone acetate and estradiol) with TYLAN (tylosin tartrate) COMPONENT TE-G (trenbolone acetate and estradiol) with TYLAN (tylosin tartrate) COMPONENT TE-ID (trenbolone acetate and estradiol) with TYLAN (tylosin tartrate)	522.2477

200-224	COMPONENT T-H (trenbolone acetate) with TYLAN (tylosin tartrate) COMPONENT T-S (trenbolone acetate) with TYLAN (tylosin tartrate)	522.2476
200-343	HEIFERMAX 500 (melengestrol acetate) Liquid Premix	558.342
200-346	COMPONENT TE-H (trenbolone acetate and estradiol) COMPONENT TE-H (trenbolone acetate and estradiol) with TYLAN (tylosin tartrate) COMPONENT TE-IH (trenbolone acetate and estradiol) COMPONENT TE-200 (trenbolone acetate and estradiol) COMPONENT TE-200 (trenbolone acetate and estradiol) with TYLAN (tylosin tartrate)	522.2477
200-375	HEIFERMAX 500 (melengestrol acetate) Liquid Premix / RUMENSIN (monensin) / TYLAN (tylosin phosphate)	558.342
200-422	HEIFERMAX 500 (melengestrol acetate) Liquid Premix plus RUMENSIN (monensin)	558.342
200-424	HEIFERMAX 500 (melengestrol acetate) Liquid Premix / OPTAFLEXX (ractopamine HCI) / RUMENSIN (monensin) / TYLAN (tylosin phosphate)	558.500
200-427	HEIFERMAX 500 (melengestrol acetate) Liquid Premix plus TYLAN (tylosin phosphate)	558.342
200-430	HEIFERMAX 500 (melengestrol acetate) Liquid Premix / BOVATEC (lasalocid) / TYLAN (tylosin phosphate)	558.342
200-448	HEIFERMAX 500 (melengestrol acetate) Liquid Premix / OPTAFLEXX (ractopamine HCl) / RUMENSIN (monensin)	558.500
200-451	HEIFERMAX 500 (melengestrol acetate) Liquid Premix plus BOVATEC (lasalocid)	558.342
200-479	HEIFERMAX 500 (melengestrol acetate) Liquid Premix / ZILMAX (zilpaterol) / RUMENSIN (monensin)	558.665
200-480	HEIFERMAX 500 (melengestrol acetate) Liquid Premix / ZILMAX (zilpaterol) / RUMENSIN (monensin) / TYLAN (tylosin phosphate)	558.665
200-483	HEIFERMAX 500 (melengestrol acetate) Liquid Premix plus ZILMAX (zilpaterol)	558.665

Accordingly, the Agency is amending the regulations in parts 522 and 558 (21 CFR parts 522, and 558) to reflect the transfer of ownership.

Following these changes of sponsorship, Ivy Laboratories, Division of Ivy Animal Health, Inc., is no longer the sponsor of an approved application. Accordingly, § 510.600 (21 CFR 510.600) is being amended to remove the entries for this firm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 522, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In §510.600, in the table in paragraph (c)(l), remove the entry for "Ivy Laboratories, Div. of Ivy Animal Health, Inc."; and in the table in paragraph (c)(2), remove the entry for "021641".

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.840 [Amended]

4. In paragraph (b) of § 522.840, remove "021641" and in its place add "000986".

§ 522.842 [Amended]

5. In paragraph (a)(2) of § 522.842, remove "021641" and in its place add "000986".

§ 522.1940 [Amended]

6. In paragraph (a)(2) of § 522.1940, remove "021641" and in its place add "000986".

§ 522.2476 [Amended]

7. In paragraph (b)(l) of § 522.2476, remove "021641" and in its place add "000986".

§ 522.2477 [Amended]

8. In paragraph (b)(l) of § 522.2477, remove "021641" and in its place add "000986".

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

9. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.342 [Amended]

10. In § 558.342, in paragraph (b)(2) and in the "Sponsor" column of the table, in paragraphs (e)(l)(i), (e)(1)(ii), (e)(l)(iii), and (e)(l)(ix) remove "021641" and in its place add

"000986"; in paragraphs (e)(1)(iv) and (e)(1)(x) add "000986"; and in paragraph (e)(1)(xi), remove "02164" and in its place add "000986".

§ 558.500 [Amended]

11. In § 558.500, in the "Sponsor" column of the table, in paragraphs (e)(2)(viii) and (e)(2)(x), remove "021641".

§ 558.665 [Amended]

12. In § 558.665, in the "Sponsor" column of the table, in paragraphs (e)(2), (e)(4), and (e)(6), remove "021641" and in its place add "000986".

Dated: May 23, 2012.

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Office of New Animal Drug Evaluation,

Center for Veterinary Medicine.

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